# Attachment 4

JUL 1 2002

## 510(k) Summary

k021825

**Surgical Dynamics Spiral Radius 90-D™ SST System**

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United States Surgical
150 Glover Avenue
Norwalk, CT 06856
USA

### DEVICE DESCRIPTION

The Spiral Radius 90-D™ SST System consists of stainless steel rods attached to the spinal column through the use of hooks. Screws may be used to attach rods to the spinal column in certain select patients and certain select levels (See Indications). Cross-bars may be used to connect rods to rods to provide a more rigid construct, as well as screws to rods, and hooks to rods. Screws and hooks are provided in several sizes to accommodate varying patient morphology.

### INDICATIONS FOR USE

The components of the Spiral Radius 90-D™ SST System are indicated for spinal fixation.

When used as an anterolateral/anterior system consisting of rods and screws, the levels of attachment are the lumbar, thoracic and cervical spine. The points of attachment and methods are screw fixation to the anterolateral vertebral bodies of the lumbar and thoracic spine (T6-L5) and the anterior vertebral bodies of the cervical spine. The Indications are degenerative disc disease defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumor, pseudoarthrosis, or failed previous fusion (pseudoarthrosis).

When used as a nonpedicle posterior system consisting of hooks, crosslinks and sacral/iliac screws the levels of attachments are the lumbar, thoracic and cervical spine and sacrum and ilium. Intended uses include hook and sacral screw fixation to the lumbar spine, noncervical spine and to the T1-S1 spine; and hook and sacral/iliac screw fixation to the noncervical spine. The indications are degenerative disc disease defined as back pain of discogenic origin with degenerative of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, deformities (i.e., scoliosis, kyphosis, lordosis), tumors, pseudoarthrosis, or failed previous fusion (pseudoarthrosis).

When used as a pedicle screw system, in the non-cervical spine of skeletally mature patients, The Spiral Radius 90-D™ SST System is indicated for patients: (a) having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of solid fusion mass.

In addition, when used as a pedicle screw system, in the non-cervical spine of skeletally mature patients, the Spiral Radius 90-D™ SST System is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion, in the treatment of the following acute and chronic instabilities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis).

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## SUBSTANTIAL EQUIVALENCE*

The modified components of the Surgical Dynamics Spiral Radius 90-D™ SST System was claimed to be substantially equivalent* to the currently marketed version of the device. Information pertaining to this device was provided in the submission.

*Any claim of substantial equivalence is made exclusively in regard to the U.S. Food, Drug and Cosmetic Act and should not be viewed in any other light.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Ms. Tina Rideout
Regulatory Affairs Senior Associate
United States Surgical
Surgical Dynamics
150 Glover Avenue
Norwalk, Connecticut 06856

Re: K021825
Trade/Device Name: Spiral Radius 90-D™ SST System
Regulation Number: 21 CFR 888.3050, 888.3060 and 888.3070
Regulation Name: Spinal interlaminal fixation orthosis, Spinal intervertebral body fixation orthosis, Pedicle screw system, Spondylolisthesis spinal fixation device system
Regulatory Class: II
Product Code: KWP, KWQ, MNH, MNI
Dated: June 3, 2002
Received: June 4, 2002

Dear Ms. Rideout:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Attachment 2

## Indications for Use Statement

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**510(k) Number** K021825

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**Indications For Use**

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(Please do not write below this line - continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X OR Over-The-Counter Use: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021825